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Harold, here is the revised fact sheet (mostly Tarplin, I guess). It just arrived this minute. Tarplin has a copy and so does Kevin Thurm. I will be around, as noted earlier, to create the "final". Let me know what you think of this. I have not read it yet. Lana has a copy.

-----Original Message-----
From: Bill Hall [SMTP:bhall@os.dhhs.gov]
Sent: Friday, January 15, 1999 5:59 PM
To: at9m@NIH.GOV
Subject: stem cell fact sheet

FACT SHEET ON STEM CELL RESEARCH

The Department of Health and Human Services has concluded that current law permits federal funds to be used for research utilizing human pluripotent stem cells. This decision is consistent with existing congressional restrictions on human embryo research and with federal law and regulations governing human fetal tissue research. The National Institutes of Health plans to move forward in a careful and deliberate fashion to develop rigorous guidelines that address the special ethical, legal, and moral issues surrounding this research. The NIH will not be funding any research using pluripotent stem cells until guidelines are widely disseminated to the research community and a review process is in place.

The Promise of Stem Cell Research

Scientists at the University of Wisconsin and another group of scientists at Johns Hopkins University recently have isolated and successfully cultured human pluripotent stem cells and have grown these cells for prolonged periods in culture dishes. Human pluripotent stem cells are cells of a human organism that have an unlimited capacity to divide, and the ability to turn into most of the cells or tissues in the body.

This exciting advance represents a huge step forward in human biology and has generated tremendous enthusiasm among scientists and the public, particularly patients and their families. Because these cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, blood cells, and others, they are enormously important to science and hold great promise for advances in health care. For example,

further research using pluripotent stem cells can help us:

ò Generate cells and tissue that could be used for transplantation. Pluripotent stem cells can be stimulated to develop into specialized cells, which can be used as replacement cells and tissue to treat many diseases and conditions including Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis.

ò Improve our understanding of the complex events that occur during normal human development and also help us understand what goes wrong to cause birth defects and cancer.

ò Change the way we develop drugs and test them for safety.
Rather than evaluating the safety of candidate drugs in an animal model, the drugs could be initially tested against a human cell line; only the safest candidate drugs would be likely to graduate to animal and then human testing.

Legal Issues

The stem cells produced by the scientists in Wisconsin and Maryland were developed by different methods. The Wisconsin scientists derived the pluripotent stem cells from early-stage embryos donated by persons through infomed consent who were undergoing fertility treatment in an in vitro fertilization (IVF) clinic. The scientists at Johns Hopkins University isolated the pluripotent stem cells from non-living fetuses obtained from terminated pregnancies. Neither research project utilized federal funds. Because of the regenerative capacity of pluripotent stem cells, these cells alone could supply numerous other researchers without the need to generate a new line of cells.

Federal law currently prohibits the NIH from funding human embryo research. In light of this legislative ban, the Director of the NIH sought a legal opinion from the DHHS Office of the General Counsel on whether federal funds may be used for research utilizing human pluripotent stem cells.

After a thorough analysis of the law, DHHS concluded that the congressional prohibition on the use of DHHS funds for certain types of embryo research does not apply to research utilizing human pluripotent stem cells because, such cells are not an embryo as defined by statute. Moreover, because pluripotent stem cells do not have the capacity to develop into a human being, they cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term. The legal opinion also clarified that pluripotent stem cells derived from non-living fetuses would fall within the legal definition of human fetal tissue and are, therefore,

subject to certain Federal restrictions on the use of such tissue.

Thus, research using pluripotent stem cells derived from human embryos can be funded by DHHS. Research that generates and uses pluripotent stem cells from non-living fetuses can also be supported by DHHS, subject to existing law and regulation.

NIH SUPPORT

In view of the tremendous scientific and medical benefits that may result from research using pluripotent stem cells, the NIH plans to consider grant applications for research using these cells. It is essential that the Federal government play a role in funding and overseeing the conduct of this research so that all scientists-- both privately and federally funded--have the opportunity to pursue this important line of research. Federal funding will help provide oversight and direction that would be lacking if this research were the sole province of industry and academe.

The NIH understands and respects the compelling ethical, legal, and moral issues surrounding pluripotent stem cell research and is sensitive to the need for stringent oversight of this research that goes beyond the traditional rigorous NIH scientific peer review process. In light of these issues, the NIH plans to move forward in a careful way prior to funding any research utilizing pluripotent stem cells. The NIH will develop and issue guidelines regarding special considerations that must be met in conducting such research, including an assurance that the research is consistent with current federal law governing embryo research. Also, the NIH will convene a special oversight group to review all research grant applications in this area, in addition to the rigorous scientific and programmatic reviews that all NIH-funded research currently undergoes. The NIH has asked the National Bioethics Advisory Board (NBAC) for additional guidance, and those views will be factored into the process of approving research proposals. The NIH will not be funding any research using pluripotent stem cells until guidelines are widely disseminated to the research community and a review process is in place.